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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,267	08/10/2001	Christopher D. Creech	018512-006510US	6230

20350 7590 04/08/2003

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EXAMINER
LI, RUIXIANG

ART UNIT	PAPER NUMBER
1646	16

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/927,267	CREECH ETAL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *10-18 and 21-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 19, and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *13* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

I. Status of Application, Amendments, and/or Claims

The amendment filed in Paper No. 15 on January 21, 2003 has been entered in full. Claims 1, 5, and 7-9 have been amended. Claims 1-40 are pending. Claims 1-9, 19, and 20 are under consideration.

Applicants' confirmation on the species election of SEQ ID NOS: 12 and 13 to prosecute claim 5 is acknowledged.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

II. Withdrawn Rejections

The rejection of claims 5-7 and 9 under 35 U.S.C. § 112, 2nd paragraph, as set forth at pages 9-10 of the previous Office Action (Paper No. 12, July 11, 2002), has been withdrawn in view of applicants' amendment to the claims.

The rejection of claim 9 under 35 U.S.C. § 102 (a), as set forth at page 10 of the previous Office Action (Paper No. 12, July 11, 2002), has been withdrawn in view of applicants' amendment to the claim.

The objection of claims 1, 5, 7, and 8 for minor informalities, as set forth at page 10 of the previous Office Action (Paper No. 12, July 11, 2002), has been withdrawn in view of applicants' amendment to the claims.

III. 35 U.S.C. § 101

The rejection of claims 1-9, 19, and 20 under 35 U.S.C. §101, as set forth at pages 3-6 of the previous Office Action (Paper No. 12, July 11, 2002), remains.

Applicants argue that prediction of orthologous polypeptide function based on high level of overall sequence homology is reliable and that the homology, combined with the observation that the two genes have similar expression patterns, demonstrates to those of skill in the art that CNG2B is the human ortholog of the rat gene and has similar biological functions.

This has been fully considered but is not deemed to be persuasive because 35 USC §101 requires disclosure of a specific, substantial, and credible utility. Such a patentable utility has to be a "real world " context of use which does not require significant further research. The instant disclosure asserts that the human CNG2B gene shows homology with rat OCNC2 and that the amino acid sequence of human CNG2B is 93% identical to that of rat OCN2. However, the instant disclosure fails to provide any experimental data or information on whether the CNG2B protein functions like a cyclic nucleotide-gated channel. While the amino acid sequence encoded by human CNG2B shares 93% homology with that of rat OCNC2, they are still not the same molecules. While sequence analysis is important, the information provided or "predicted" based upon sequence homology can only be used as guidance in determining functions or activities of a molecule by experiments. The similar expression patterns for the human CNG2B and rat OCNC2 does not necessarily provides a convincing evidence that CNG2B is the human ortholog of the rat gene. In this regard, what Bork and Koonin teach is that careful sequence analysis can enhance the capability for function

prediction whereas prediction of function using comparative sequence analysis may lead to the creation and propagation of assignment errors if not performed appropriately. In addition, any functions predicted based upon the sequence homology will have to be confirmed ultimately by bench work and have experimental support. Such confirmation whether the claimed nucleic acid encodes a functional CNG2B requires undue experimentation. See *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966), noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."

The Response argues that claims directed to fully characterized proteins or encoding nucleic acids meet the utility requirement of 35 U.S.C. § 101, citing an example in the "Guidelines for Examination of Applications for compliance with the Utility Requirement".

This has been fully considered but is not deemed to be persuasive because the instant disclosure fails to functionally characterize the CNG2B polypeptide and fails to disclose a specific and substantial utility for the claimed invention. Since the CNG2B lacks well-defined biological functions and a specific and substantial utility, the nucleic acid encoding the CNG2B also lacks a patentable utility. In contrast, the compound A referred in Example 8 and cited by the applicants has a patentable utility because it inhibits a well-known enzyme, which has a well-established utility. It is not the case here.

In summary, the disclosure fails to provide a specific, substantial, and credible utility, or a well-established utility.

IV. Claim Rejections Under 35 U. S. C. § 112, 1st Paragraph (Enablement)

The rejection of claims 1-9, 19 and 20 under 35 U.S.C. § 112, 1st paragraph remains. The basis for this rejection is set forth at pages 6-7 of the previous Office Action (Paper No. 12, July 11, 2002).

Applicants' arguments about the patentable utility of the claimed invention has been fully considered but is not deemed to be persuasive for reason set forth above.

The scope enablement rejection set forth in the previous Office Action (Paper No. 12, July 11, 2002) also remains. The previous office action states that even if the nucleic acid molecules of SEQ ID NOS: 2 and 3 or encoding the amino acid sequence of SEQ ID NO: 1 were to have a patentable utility, the instant disclosure would not be found to be enabling for the full scope of the claimed invention. In other words, if the claimed invention were to have a patentable utility, the nucleic acid molecules of SEQ ID NOS: 2 and 3 or encoding the amino acid sequence of SEQ ID NO: 1 would be enabled, as applicants argued. However, the homologues, variants, alleles, and mutants of the CNG2B nucleic acid would not be enabled.

Applicants argue that the claims of the present invention are directed to nucleic acids encoding a subunit of a CNG2B cation channel with a well-defined structure and readily testable functional feature (2nd paragraph of page 8 of applicants response) and that the disclosure is sufficiently enabling for an artisan to practice the invention and no undue experimentation is required (1st paragraph of page 9).

This has been fully considered but is not deemed to be persuasive because the working examples and guidance provided in the instant disclosure are all directed to the nucleic acid molecules of SEQ ID NOS: 2 and 3 or encoding the amino acid sequence

of SEQ ID NO: 1. No working examples or sufficient guidance are provided on how to make and use the homologues, variants, alleles, and mutants of the CNG2B nucleic acid. In addition, since the disclosure fails to disclose any experimental evidence or sufficient information on the biological activities of the nucleic acid molecules of SEQ ID NOS: 2 and 3 or encoding the amino acid sequence of SEQ ID NO: 1, the apparent functional limitation does not effectively limit the scope of the claimed invention. While the technical level in this area of the art is high, it would still require undue experimentation for an artisan to make and use the homologues, variants, alleles, and mutants of the CNG2B nucleic acid without defined structural and functional limitations, and specific guidance.

The Examiner further clarify that claims 1-3, 5-9, 19, and 20, either directly or indirectly, recite the homologues, variants, alleles, and mutants of CNG2B nucleic acid. Therefore, they are rejected under 35 U.S.C. § 112, 1st paragraph for scope enablement as stated above.

V. Claim Rejections Under 35 U. S. C. § 112, 1st Paragraph (Written Description)

The rejection of claims 1, 3, 8, 19, and 20 under 35 U.S.C. § 112, 1st paragraph remains. Claims 5-7 and 9 are also rejected 20 under 35 U.S.C. § 112, 1st paragraph. The basis for this rejection is set forth at pages 7-9 of the previous Office Action (Paper No. 12, July 11, 2002).

Applicants argue that both structural and functional features commonly shared by the claimed genus have been described in detail and that the pending claims as

amended fully comply with the requirements for written description of a chemical genus as set forth in University of California v. Eli Lilly & Co. USPQ2d 1398 (Fed. Cir. 1997).

This has been fully considered but is not deemed to be persuasive for the following reasons.

While the instant specification provides an adequate written description for the nucleic acids of SEQ ID NOS: 2 and 3 or an nucleic acid encoding the amino acid sequence of SEQ ID NO: 1, it fails to provide adequate or sufficient written description for its homologues, variants, alleles, and mutants. There is no disclosure of examples of homologues, variants, alleles, and mutants of the CNG2B nucleic acid. There is no description of the conserved regions that are critical to the structure and function of the genus claimed. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function.

In addition, the asserted functional limitation, "encodes either a CNG2B polypeptide, or a subunit of a cation channel capable of forming, with at least one CNG alpha subunit, a cation channel with CNG characteristics", does not effectively describe the claimed genus. This is because the instant disclosure has not disclosed sufficient information on whether the CNG2B polypeptide acts as a cyclic nucleotide-gated channel.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that

[he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the homologues, variants, alleles, and mutants of the CNG2B nucleic acid, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated nucleic acids of SEQ ID NOS: 2 and 3, and the isolated nucleic acid encoding the amino acid sequence of SEQ ID NO: 1, but not the full breadth of the claim, meet the written description provision of 35 U.S.C. §112, first paragraph.

VI. Claim Rejections Under 35 U. S. C. § 112, 2nd paragraph

(i) The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(ii) Claims 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7-9 are indefinite because they recite "a cyclic nucleotide gated cation channel (CNB) 2B polypeptide". Such a name is determined arbitrarily and may change with time. Further, it is noted that CNG2B refers to CNG2B polymorphic variants, alleles, mutants, and homologues (page 10). It is suggested that the term be modified by an amino acid sequence identifier (SEQ ID NO: 1) to overcome this rejection.

VII. Claim Rejections Under 35 U. S. C. § 102 (e)

(i) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(ii) Claims 1, 3, 5-9, 19, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Raumann et al. (WO 02/02633 A2, January 10, 2002; prior application US 60/215,391; priority date, June 29, 2000).

Raumann et al. teach a nucleic acid molecule comprising a sequence that is 99.9% identical to SEQ ID NO: 3 and encodes an amino acid sequence that is 99.8% identical to SEQ ID NO: 1 (see attached sequence alignment). Thus, the complement of

the nucleic acid sequence, by its nature, would hybridise with SEQ ID NO: 2 or SEQ ID NO: 3. Raumann et al. further teach an expression vector comprising the nucleic acid, and a host cell transfected with the vector (See, e.g., Abstract). It is noted that claim 5 is drawn to a product (an isolated nucleic acid) made by a process (amplification by primers). However, such a process does not distinguish the product from the one taught in the art. Therefore, the reference of Raumann et al. meets the limitations of claims 1, 3, 5-9, 19, and 20.

(iii) Claims 1, 3, 5-9, 19, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Vernet et al. (WO 01/81578 A2, November 1, 2001; prior application US 60/201,474; prior date, May 3, 2000).

Vernet et al. teach a nucleic acid molecule (page 78) comprising a sequence that is 99.9% identical to SEQ ID NO: 3 and encodes an amino acid sequence (page 79) that is 99.8% identical to SEQ ID NO: 1 (see attached sequence alignment). Thus, the complement of the nucleic acid sequence, by its nature, would hybridise with SEQ ID NO: 2 or SEQ ID NO: 3. Vernet et al. further teach an expression vector comprising the nucleic acid and a host cell transfected with the vector (See, e.g., claims 5, 11-14). It is noted that claim 5 is drawn to a product (an isolated nucleic acid) made by a process (amplification by primers). However, such a process does not distinguish the product from the one taught in the art. Therefore, the reference of Vernet et al. meets the limitations of claims 1, 3, 5-9, 19, and 20.

VIII. Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
March 21, 2003

YVONNE EYLER, PH.D
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